B. 510(k) SUMMARY (as required by 21 CFR 807.92)

APR 17 2014

Aesculap Implant Systems, LLC. (AIS) Modulift (Modulift) VBR System
March 28, 2014

COMPANY:	Aesculap®Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Lisa M. Boyle 800-258-1946 (phone) 610-791-6882 (fax)
TRADE NAME:	AIS Modulift VBR System
COMMON NAME:	Adjustable Vertebral Body Replacement Device
CLASSIFICATION NAME:	Spinal Vertebral Body Replacement Device
REGULATION NUMBER:	888.3060
PRODUCT CODE:	MQP

PURPOSE FOR PREMARKET NOTIFICATION

The AIS Modulift VBR System described in this submission introduces new VBR's with differenct size end caps, new instruments, and device modifications that have been implemented to the existing product line cleared under K110864.

DEVICE DESCRIPTION

The AIS Modulift VBR System is an adjustable vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. The system is comprised of spacers and foot plates of various heights and sizes to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. Once it is adjusted to the desired height the column is mechanically locked in place by means of locking screws (grub screws). Each spacer has an axial hole to allow grafting material to be packed inside the device. Spikes on the end of the foot plates improve the anchoring of the implant to the vertebral body. The foot plates of the device are available in various lordotic and kyphotic angles. Components are manufactured from titanium alloy (Ti6Al4V) per ASTM F-136, and cobalt chrome (CoCr) per ASTM F1537.

INDICATIONS FOR USE

The AIS Modulift VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The AIS Modulift VBR System is intended for use with

supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. The AIS Modulift VBR System may be used with bone graft.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicates)

As is established in this submission, the AIS Modulift VBR System is a mechanically adjustable vertebral body replacement device that is substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, intended use, material composition, function and range of sizes.

PERFORMANCE DATA

~~As recommended by the~~ FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS Modulift VBR System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic compression per ASTM F2077
- Subsidence per ASTM F2267
- Wear Debris per ASTM F2077 & ASTM F1877
- Expulsion per ASTM Draft Standard F-04.25.02.02

The results of these studied showed that the subject AIS Modulift VBR System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

PREDICATE DEVICE

- ~~Aesculap Modulift~~ VBR System (K110864)
- Osteotch (Ulrich) VBR Systems (K012254/K060416)
- Globus Expand (K050850)
- DePuy X-MESH (K080568)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

Aesculap® Implant Systems, Incorporated
Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K133802
Trade/Device Name: AIS Modulift Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: March 21, 2014
Received: March 21, 2014

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133802

Device Name

AIS Modulift Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*

The AIS Modulfift VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The AIS Modulift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. The Aesculap Modulift VBR System may be used with bone graft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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